Please amend the claim as follows:

B3

1. (Once amended) A substantially purified nucleic acid molecule that encodes a cotton protein or fragment thereof comprising a nucleic acid sequence of SEQ ID NO: 1.

Please add the following new claims:

B4

10. (new) A substantially purified nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO: 1.

11. (new) A substantially purified nucleic acid molecule consisting of a nucleic acid sequence of SEQ ID NO: 1.

Remarks

I. Support for the Amendments

The specification has been amended to remove the alleged embedded hyperlinks and/or other forms of browser-executable code. Claims 2–9 have been cancelled without prejudice to, or disclaimer of the underlying subject matter. Claim 1 has been amended to recite the elected SEQ ID NO. Claims 10 and 11 have been added. Support for the foregoing amendments can be found throughout the specification, for example, at page 9, line 15 to page 10, line 2 and page 19, line 7 to page 20, line 2, in the sequence listing, and in the original claims. No new matter enters by these amendments.

II. The Restriction Requirement

Applicants acknowledge the finality of the restriction requirement and additionally the restriction requirement limiting the examination to a single sequence;

however, Applicants respectfully maintain their traversal. Office Action at page 2. Where only a relatively straightforward search is required from the Examiner, limiting the examination to a single sequence will pose an undue hardship for Applicants. However, in order to facilitate prosecution, Applicants have cancelled claims 2-9 drawn to the non-elected invention and have amended claim 1 to recite the elected SEQ ID NO: 1.

III. Rejection under 35 U.S.C. § 101

Claim 1 was rejected under 35 U.S.C. § 101, because the claimed invention is allegedly not supported by either specific and/or substantial utility or a well established utility as outlined in the Revised Interim Utility Guidelines Training Materials ("Interim Guidelines"). Applicants respectfully traverse this rejection.

The Examiner acknowledges that the specification describes multiple utilities for the present invention, including "determining the association of polymorphisms and a plant trait, use in hybridization assays, measurement of protein expression levels, detecting mutations, modifying protein expression, and use as molecular tags." Office Action at page 4. However, the Examiner contends that none of these utilities constitutes a "substantial" or "specific" utility as defined in the Interim Guidelines[1] because they are

[1] Applicants respectfully point out that the Patent Office has said the Interim Guidelines "do not constitute substantive rulemaking and hence do not have the force and effect of law. They are designed to assist Office personnel in analyzing claimed subject matter for compliance with substantive law. Rejections will be based upon the substantive law, and it is these rejections which are appealable." Department of Commerce, Patent and Trademark Office, *Request for Comments on Interim Guidelines for Examination of*

Footnote continued on next page

"non-specific uses that are applicable to nucleic acids in general and not particular or specific to the nucleic acids being claimed." *Id.*

Applicants respectfully disagree. It is well-established law that "when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown." *Raytheon Co. v. Roper Corp.,* 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983). As acknowledged by the Examiner, the specification describes multiple objectives and utilities that are met by the present invention, for example, "the isolation of genes, detection of other nucleic acid molecules, determining an Expression Response, and genetic mapping." Office Action at page 4.

Many of these uses are directly analogous to the use of a microscope. An important utility of a microscope resides in its use to identify and characterize the structure of biological tissues in a sample, cell, or organism. Significantly, the utility of a microscope under 35 U.S.C. § 101 is not compromised by its use as a tool in this manner. Many of the presently disclosed utilities are directly analogous to the utilities of a microscope, *i.e.* the claimed nucleic acid molecule may be used to identify and characterize nucleic acid molecules within a sample, cell, or organism. Such utility is indistinguishable from the legally sufficient utility of a microscope. Thus, the presently disclosed sequence possess the requisite utility under 35 U.S.C. § 101.

In the Office Action, the Examiner provides no evidence challenging the disclosed utilities for the presently claimed nucleic acid molecule. Rather, the Examiner

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Footnote continued from previous page
Patent Applications Under the 35 U.S.C. § 112(1) 'Written Description' Requirement, 63 Fed. Reg. 32639, 32639-44 (June 15, 1998).

attempts to undermine the existing utilities by stating that the disclosed uses "are generally applicable to broad classes of this subject matter." Office Action at page 4.

In short, the Examiner's rejection, as it pertains to 35 U.S.C. § 101, rests on the premise that because other molecules might be used for the same purpose, the proposed utilities for the claimed molecules are legally insufficient. This position is wrong as a matter of law – there is no requirement of exclusive utility in the patent law. *See Carl Zeiss Stiftung v. Renshaw PLC,* 945 F.2d 1173, 1180, 20 U.S.P.Q.2d 1094, 1100 (Fed. Cir. 1991) ("An invention need not be the best or the only way to accomplish a certain result...").

Moreover, this position offends the sensibilities. For example, such an argument implies that a new golf club has no legal utility because other golf clubs can be used for the same purpose, *i.e.* hitting golf balls. Such a result is not only untenable, but requires reading "into the patent laws limitations and conditions which the legislature has not expressed," a practice condemned by the Supreme Court. *See Diamond v. Chakrabarty,* 447 U.S. 303, 308, 206 U.S.P.Q. 193, 196 (1980), *quoting United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199, 17 U.S.P.Q. 154, 162 (1933). Thus, it must be the case that a utility, generic to a broad class of molecules, does not compromise the specific utility of an individual member of that class.

Applicants note that the claimed nucleic acid molecule encompasses many utilities. Furthermore, Applicants acquiesce that some of these utilities may be common to a broader class of molecules. For instance, nucleic acid sequences may generally be used to identify and isolate related sequences. However, when used in this manner, the result is not generic. Rather, the claimed nucleic acid molecule will identify a ***unique***

subset of related sequences. This subset of related sequences is specific to the claimed sequence and cannot be identified by any generic nucleic acid molecule. For example, a random nucleic acid molecule would not provide this specific utility. Referring again to the golf club analogy, the club is still generically hitting a golf ball, but is uniquely designed to hit the ball in a manner that is distinct from other clubs. Once again, Applicants assert that the claimed nucleic acid sequences exhibit the requisite utility under 35 U.S.C. § 101.

Furthermore, utility is determined "by reference to, and a factual analysis of, the disclosure of the application." *In re Ziegler*, 992 F.2d 1197, 1201, 26 U.S.P.Q.2d 1600, 1603 (Fed. Cir. 1993), *quoting Cross v. Iizuka*, 753 F.2d 1040, 1044, 224 U.S.P.Q. 739, 742 (Fed. Cir. 1985). The Examiner "has the initial burden of challenging a presumptively correct assertion of utility in the disclosure." *In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). The utilities asserted in the specification must be accepted as factually sound unless the Patent Office cites information that undermines the credibility of the assertion. *Id.* The Examiner "must do more than merely question operability – [he] must set forth factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability." *In re Gaubert,* 524 F.2d 1222, 1224-25, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975) (emphasis in original); MPEP § 706.03(a)(1) ("Office personal are reminded that they must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided…").

Here, the Examiner has not set forth factual reasons that question the objective truth of the proposed utilities. The Examiner casts doubt that the sequence is specific to

the tissue type or particular stage of growth from which it was isolated. Office Action page 4. However, the Examiner does not provide factual evidence to support his opinion, nor do the proposed utilities require the claimed sequence to be specific to the particular tissue type or stage of growth from which it was isolated. Thus, because the Examiner does not make a credible challenge of the disclosed utilities, the burden has not been met, and the rejection is improper.

In view of the above, Applicants contend that the claimed nucleic acid molecules are supported by credible, specific, and substantial utilities disclosed in the specification. Moreover, the Examiner has failed to raise any credible evidence challenging the presently asserted utilities. Consequently, the rejection of claim 1 under 35 U.S.C. § 101 is improper. Reconsideration and withdrawal of this rejection are respectfully requested.

IV. Rejection of Claims 1 and 2, Under 35 U.S.C. § 112, First Paragraph

In the Office Action, at page 5, the Examiner has rejected claim 1 as not being enabled by the specification, because the claimed invention allegedly lacks utility. Applicants respectfully traverse this rejection and contend that this rejection has been overcome by the foregoing arguments regarding utility. Thus, the enablement rejection under 35 U.S.C. § 112, first paragraph is improper. Reconsideration and withdrawal are respectfully requested.

V. Rejection of Claim 1 Under 35 U.S.C. § 112, First Paragraph

In the Office Action, at pages 6–7, the Examiner has rejected claim 1 under 35 U.S.C. § 112, first paragraph, containing subject matter which was not described in the

specification in a manner that reasonably conveys to one of ordinary skill in the art that the inventors had possession of the claimed invention at the time of filing. This rejection is respectfully traversed for at least the reasons that follow.

An adequate written description of a genus of nucleic acids, such as recited in claim 1, may be achieved by either "a recitation of a representative number of [nucleic acid molecules], defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus." *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568-69 (Fed. Cir. 1997). The feature relied upon to describe the claimed genus must be capable of distinguishing members of the claimed genus from non-members. *Id.*

As the Examiner notes, the purpose of the written description requirement is to ensure that the inventors had possession of the claimed subject matter, *i.e.*, to ensure that the inventors actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). In accordance with this purpose, Applicants need not "describe," in the sense of Section 112, all things that are encompassed by the claims. To contend otherwise would contradict established jurisprudence, which teaches that a patent may be infringed by technology developed after a patent issues. *United States Steel Corp. v. Phillips Petroleum Co.*, 865 F.2d 1247, 1251, 9 U.S.P.Q.2d 1461, 1464 (Fed. Cir. 1989). A related, and equally well-established principle of patent law is that claims "may be broader than the specific embodiment disclosed in a specification." *Ralston Purina Co. v. Far-mor-Co*, 772 F.2d 1570, 1575,

227 U.S.P.Q. 177, 179 (Fed. Cir. 1985), *quoting In re Rasmussen*, 650 F.2d 1212, 1215, 211 U.S.P.Q. 323, 326 (C.C.P.A. 1981). Thus, in order for Applicants to describe each and every molecule encompassed by the claims, it is not required that every aspect of those nucleic acid molecules (*e.g.*, an open reading frame) be disclosed. *In re Alton,* 76 F.3d 1168, 1175 (Fed. Cir. 1996) (if a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing even if every nuance of the claims is not explicitly described in the specification).

The Examiner contends that the skilled artisan cannot envision the detailed chemical structure of the genus encompassed by the claim. Office Action at page 6. According to the Examiner's argument, proper written description support for a claim directed to a nucleic acid sequence requires nothing less than the actual disclosure of every sequence encompassed by that claim. In support of this proposition, the Examiner relies on *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 43 U.S.P.Q.2d 1398 (Fed. Cir. 1997). Office Action at pages 6 and 7. Applicants respectfully disagree. In *Eli Lilly* the court found that claims to a vertebrate cDNA coding insulin were inadequately described. However, the present case is clearly different. Specifically, the present claims "distinguish the claimed genus from others" and define "structural features commonly possessed by members of the genus that distinguishes them from others," unlike the claims at issue in *Eli Lilly. Id.* at 1568-69 ("a cDNA is not defined or described by the mere name 'cDNA'...but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the DNA.").

In particular, Applicants have provided a detailed chemical structure, *i.e.*, the nucleic acid sequence of SEQ ID NO: 1. Moreover, nucleic acid molecules falling within the scope of the present claims are readily identifiable – they comprise a nucleic acid molecule having the sequence selected from the group consisting of SEQ ID NO: 1. The fact that the nucleic acid molecules may comprise additional sequences or variations is beside the point. Such modifications are readily envisioned by one of ordinary skill in the art and disclosed through the present specification. Thus, there is no deficiency in the written description support for claim 1 and SEQ ID NO: 1. Thus, claim 1 satisfies the written description requirement of 35 U.S.C. § 112, first paragraph. Reconsideration and withdrawal of this rejection are respectfully requested.

Conclusion

Applicants respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. As such, Applicants believe the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Applicants do not believe that extensions of time or fees for net addition of claims are required beyond those that may otherwise be provided for in the documents accompanying this paper. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefor (including fees for net addition of claims) are hereby authorized to be charged to our Deposit Account Number 50-1824, referencing docket number 38-21(51375)B. Applicants likewise authorize a charge to Deposit Account Number 50-1824 for any other fees related to the present application that are not otherwise provided for in the accompanying documents.

Respectfully submitted,

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Version with markings to show changes made

In the specification:

At page 5, lines 8 to 17:

Similarity analysis includes database search and alignment. Examples of public databases include the DNA Database of Japan (DDBJ) ([http://]www[.]-ddbj.nig.ac.jp/); Genebank ([http://]www[.]-ncbi.nlm.nih.gov/Web/Genebank/Index.html); and the European Molecular Biology Laboratory Nucleic Acid Sequence Database (EMBL) ([http://]www[.]-ebi.ac.uk/ebi_docs/embl_db.html). A number of different search algorithms have been developed, one example of which are the suite of programs referred to as BLAST programs. There are five implementations of BLAST, three designed for nucleotide sequence[s] queries (BLASTN, BLASTX and TBLASTX) and two designed for protein sequence queries (BLASTP and TBLASTN) (Coulson, *Trends in Biotechnology*, *12*:76-80 (1994); Birren, *et al. Genome Analysis, 1*: 543-559(1997)).

At page 28, lines 11 to 18:

A PCR probe is a nucleic acid molecule capable of initiating a polymerase activity while in a double-stranded structure with another nucleic acid. Various methods for determining the structure of PCR probes and PCR techniques exist in the art. Computer generated searches using programs such as Primer3 (available on the World Wide Web at [www-]genome.wi.mit.edu/cgi-bin/primer/primer3.cgi), STSPipeline (available on the World Wide Web at [www-]genome.wi.mit.edu/cgi-bin/www-STS_Pipleine) or GeneUp (Pesole *et al., BioTechniques 25*:112-123 (1998) the entirety of which is herein incorporated by reference), for example, can be used to identify potential PCR primers.

In the claims:

1. (once amended) A substantially purified nucleic acid molecule that encodes a cotton protein or fragment thereof comprising a nucleic acid sequence [selected from the group consisting] of SEQ ID NO: 1[through SEQ ID NO: 52949].

10. (added) A substantially purified nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO: 1.

11. (added) A substantially purified nucleic acid molecule consisting of a nucleic acid sequence of SEQ ID NO: 1.